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# EXPERIMENTATION ON HUMAN BEINGS

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*The forthcoming revision of the Medico-Moral Problems series of booklets by Father Gerald Kelly, S.J., published by The Catholic Hospital Association, will include the following chapter in its contents. THE LINACRE QUARTERLY has Father Kelly's permission to preview the material in this issue of the journal.*

Even medical treatments of proved worth are sometimes accompanied by risk because of the unpredictable reactions of the patient. Avoidance of such risks for the patient is one purpose of the careful diagnosis required by medical societies; and avoidance of similar risks for others is one purpose of the autopsy. Yet, even the utmost care cannot completely eliminate such risk; and it is not to this kind of risk that the expression "medical experimentation" refers. Rather, experimentation usually means either the use of treatments not sufficiently established or the use of procedures which have for their precise purpose the discovery of some truth or the verification of some hypothesis. In the present chapter I am following this usual meaning, and I am supposing that the experimentation involves some degree of inconvenience or risk for the subject.

In general, the purposes of medical experimentation are two: to benefit the subject (e.g., the patient) or to advance medical science and thus benefit others than

the subject. When we speak of experimentation for the good of the patient, we mean primarily for the good of the patient; and that is the meaning of the first part of n. 42 of *Ethical and Religious Directives for Catholic Hospitals*.<sup>1</sup> The directive does not, however, absolutely rule out experimentation which is primarily or even exclusively for the good of others, provided the patient consents and the precautions to be explained later are observed. My subsequent remarks will be concerned with both kinds of experimentation: namely, for the good of the patient; and for the good of others.

## FOR THE GOOD OF THE PATIENT

Experimental procedures are, by supposition, of dubious efficacy. Theology manuals generally give three rather simple rules for the use of such procedures: (1) they may not be used if a certainly effective remedy is available; (2)

<sup>1</sup> "n. 42 Experimentation on patients without due consent and not for the benefit of the patients themselves is morally objectionable. Even when experimentation is for the genuine good of the patient, the physician must have the consent, at least reasonably presumed, of the patient or his legitimate guardian."

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when the only available treatments are of dubious efficacy, then the one most likely to help the patient should be used; and (3) the consent, at least, reasonably presumed, of the patient or his legitimate representative must be had.

Only the third of these rules is an absolute. The first two rules are subject to exceptions. For example, if the one certainly effective remedy for a disease is a long, difficult, and very expensive procedure, the patient may try to avoid these inconveniences by resorting to a less certain, but also less inconvenient, treatment. In a word, the patient may take the risk of a less certain remedy provided there is a proportionate reason for it. This is in keeping with the general principle enunciated in the first part of directive 40: "any procedure harmful to the patient is morally justified only insofar as it is designed to produce a proportionate good." And it is also in conformity with the provision of directive 42 that experimentation must be "for the genuine good of the patient." If this principle of proportionate reason or genuine good is conscientiously observed, there should be no great difficulty in determining when experimentation may be used in the interests of the patient.

## FOR THE GOOD OF OTHERS

The literature, both medical and theological, on experimentation for the good of others is so vast that I could not even attempt to cover it in a short chapter. My plan is to review one representative set of scientific articles and to compare

the conclusions with the teaching of Pope Pius XII. I shall add some remarks on abuses and on standards of the medical profession.

## I. Articles in Science:

The articles that I have chosen as representative of scientific literature, were published under the general title, "The Problem of Experimentation on Human Beings," in *Science*, Feb. 27, 1953, pp. 205-215. These articles, four in number, are based on a symposium held at the University of California School of Medicine. They are mainly concerned with experimentation for the advancement of science on normal healthy persons or the incurably and fatally ill. As regards healthy individuals, it is conceded that no experiment should be conducted until the experimenters are in possession of the most thorough information available from animal and clinical studies; and in the case of the incurably ill, palliation must be the first medical consideration. Experimentation, therefore, must be understood within these limits.

In the first article, "The Research Worker's Point of View," Michael B. Shimkin outlines the whole problem, cites the rules for human experimentation formulated by the Tribunal at Nuremberg, refers to similar rules adopted by medical committees, and says:

Analysis of the rules shows that they can be reduced to two primary principles: First, the investigators must be thoroughly trained in the scientific disciplines of the problem, must understand and appreciate the ethics involved, and must thus be competent to undertake and to carry out the experiment. Second, the human

experimental subject must understand and voluntarily consent to the procedure, and must not be selected upon any basis such as race, religion, level of education, or economic status. In other words, *the investigators and the subjects are human beings with entirely equal, inalienable rights that supersede any considerations of science or general public welfare.*

Giving "The Physician's Point of View," Otto E. Guttentag explicitly discusses the type of experiment on the sick which "is of no immediate value to the patient but is made to confirm or disprove some doubtful or suggested biological generalization." He believes such experimentation to be necessary; yet he points to the fact that the conducting of the experiment conflicts with the traditional role of the physician as the friend and helper of the sick man, and the physician must be extraordinarily careful to preserve the attitude of "utmost concern" for the patient's welfare.

The lawyer's side of this question is given by Alexander M. Kidd in the third article, "Limits of the Right of a Person to Consent to Experimentation on Himself." He stresses the legal need of consent by any subject for experimentations; suggests that it is not a matter of good public relations for physicians to use any procedure on a patient that is not for the patient's benefit; and states two general limits to the rights of persons to permit experimentations that are not for their benefit: i.e., one may not consent either to one's own death or to an injury amounting to a maim. In the last article, "Civil Rights of Military Personnel Regarding Medical Care and Experimental Proce-

dures," Colonel W. H. Johnson cites a military regulation which he believes might be the basis for authorizing the use of volunteer military personnel for experimentation, but he adds: "Needless to say, the Medical Department would not receive volunteers in this field if it considered the experimentation unduly hazardous or unnecessary."

The foregoing paragraphs express the main lines of thought in the *Science* articles. They lead I believe, to a conclusion which may be expressed thus: experimentation on the healthy or incurably ill should, or at least may, be permitted for the good of others and the advancement of science, provided (a) that the subject freely consents, (b) that no experiment which directly inflicts grave injury or death is used, and (c) that all reasonable precautions are taken to avoid even the indirect causing of grave injury or death.

## 2. Teaching of Pius XII:

In his address to the histopathologists (Sept. 13, 1952) and later in his discourse to delegates to the Eighth Congress of the World Medical Association (Sept. 30, 1954), Pope Pius XII spoke at great length about experimentation which is primarily or exclusively for the good of others. It will be interesting to compare his teaching with the conclusion drawn from the *Science* articles.

The Pope laid great stress on the dignity of the individual and on his personal responsibility for the care of his health. From this it follows that the individual's con-

sent, at least tacit, must be had for any medical treatment, whether therapeutic or experimental. On this point there is perfect agreement between the *Science* articles and the papal teaching.

The individual, said the Pope, is only the administrator of his life and bodily members and functions; and, because he is only the administrator, his power to dispose of these things is limited. Thus, even as regards treatments for his own good, he must observe the law of "hierarchy of values" — for example, he may not permit an operation which would completely deprive him of the use of his higher faculties, such as freedom and intellectual cognition, merely to cure some bodily or emotional ailment. And, as regards experimental procedures for the good of others, no individual has the right to permit things which would "entail, either immediately or subsequently, serious destructions, mutilations, wounds, or dangers." These words were used in the address to the histopathologists. More comprehensive and more detailed is the following statement taken from the discourse of Sept. 30, 1954:

What goes for the doctor in regard to his patient goes also for the doctor in regard to himself. He is subject to the same great moral and juridical principles. He cannot, therefore, submit himself to scientific experiments or practices that entail serious harm or threaten his health. Still less is he authorized to attempt an experiment, which, according to authoritative information, may involve mutilation or suicide. The same must be said, furthermore, of male and female nurses and of anyone who may be disposed to give himself to therapeutic research. They cannot submit themselves to such experiments.

From the foregoing it is clear that the papal teaching sets limits

to what the subject of an experiment may permit and that it condemns the attitude of extreme individualism which holds that, granted a person freely consents to an experiment, there is practically no limit to what may be done. There may be some differences of opinion as to the precise limits permitted by the Pope; but it seems to me that there is no conflict between his teaching and the limitations defined by the *Science* articles.

It is very important that those engaged in medical research and experimentation have sound philosophical attitudes toward man, his nature, his rights, and his destiny. Pius XII emphasized this and strongly condemned two false attitudes. One of these attitudes is the extreme individualism mentioned in the preceding paragraph. Another is the totalitarian attitude, the view that the individual exists for the community and is subordinated to it as part to whole. The most glaring example of this disastrous attitude is the experimentation carried on by the Nazi doctors. Civilization looks with horror on these experiments; nevertheless, as Pius XII has very often said or implied, the totalitarian attitude did not die with the execution of the War criminals. In condemning this attitude, the Pope clearly taught that the individual is not a subordinate part of society in the same way, e.g., as the hand is a part of the physical body; and, as a consequence of this, it is wrong to invoke the principle of totality to justify medical experimentation for the advancement of

science or for the good of others.

The *Science* articles do not, of course, make explicit mention of the principle of totality, because that expression is a strictly theological one. Nevertheless, they do insist on the dignity of the individual and on the fact that he has inalienable rights that supersede any considerations of science or general public welfare. This is substantially the same, it seems to me, as saying that the individual is not subordinated to society as part to whole; hence, on this point, there is no difference between the philosophy underlying the articles and the papal teaching.

My conclusion from a comparison of the *Science* articles with the papal teaching is that they do not differ substantially;<sup>2</sup> hence, the points previously given as the conclusion of the articles may also be used as concrete statements of the teaching of Pius XII.

### 3. Abuses versus standards:

What I have written should not be taken as a "whitewashing" of abuses by clinical investigators and research workers. That there are real abuses is clear to me both from my reading and from what I have been told by doctors. These abuses mainly consist in doing things without consent or in practically forcing the consent of "charity" patients; but in some cases risks are apparently taken that would not be justified even with consent. For example, some small things done without consent

<sup>2</sup>I say "substantially," because there are some *obiter dicta* concerning abortion, euthanasia, and sterilization that are not above suspicion.

might be making certain tests with a needle or practicing with some instrument such as a proctoscope. These things are done, not for the good of the patient, but to build up statistics or to give young doctors practice. Such things do the patient no harm but they do annoy him. Other abuses concern more serious matters: transfusions with blood from a person with a serious blood disease; giving hormones or vaccine to one group that might be harmed and withholding the same from a group that may need them — all for the purpose of having "control groups" for research projects. I would not want to say that these or similar abuses are common, but I have good reason to believe that they are not entirely uncommon. And that the Pope was conscious of such abuses, and perhaps much more serious ones, is evident from his address to the histopathologists.

In fairness to the medical profession, it should be said that these abuses must be attributed to individuals' attitudes and conduct and not to published professional standards. I have read many professional statements and have found in them little or nothing that could be considered morally objectionable. For example, the rules for experimentation on human beings used at the Nuremberg medical trials contain such points as these: the absolute need of the enlightened consent of the human subject; the preliminary use, as far as possible, of animal experimentation and other methods of study; the sound hope of fruitful results, with due proportion between this

and the risk involved; avoidance of any experiment when there is an *a priori* reason to believe that death or disabling injury will occur; the use of all possible precautions against injury; the complete liberty of the human subject to terminate the experiment at any time when he thinks his physical or mental state requires it; and the sincere willingness of the scientist to terminate the experiment at any stage when its continuation is likely to result in injury, disability, or death for the subject. It seems to me that there is no conflict be-

tween these provisions and the teaching of Pius XII; rather, they seem to make his teaching more concrete.<sup>3</sup>

<sup>3</sup>The text in the ten rules is given in THE LINACRE QUARTERLY, Nov., 1953, pp. 114-115. Rule 5 reads as follows: "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects." This tentative admission that the moral limits might be extended when the experimenters themselves are the subjects is the only point that seems to conflict in any way with the teaching of Pius XII.



The Catholic Physicians' Guild of North Central Montana, Great Falls, will observe a time-honored custom in the homes of the members. The "Advent Wreath" ceremony will help their families prepare for the coming of Christmas. The preparation and blessing of the wreath and weekly devotions are explained in mimeographed sheets available for distribution. A note to Robert J. McGregor, M.D., Guild president, McGregor Clinic, Ford Building, Great Falls, Montana, asking for a copy will receive attention. This lovely practice is observed in many homes.

